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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,680	01/22/2002	Carl Johan Friddle	LEX-0301-USA	5215

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LEXICON GENETICS INCORPORATED
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THE WOODLANDS, TX 77381-1160

EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT PAPER NUMBER

1647

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,680

Applicant(s)

FRIDDLE ET AL.

Examiner

Christopher J Nichols, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/14/02, 1/22/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 June 2004 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of Application, Amendments, and/or Claims

3. The Amendment filed 28 July 2003 has been received and entered in full.
4. The Amendment filed 20 February 2004 has been received and entered in full.

Withdrawn Objections And/Or Rejections

5. The Rejection of claim 2 under 35 U.S.C. §112 ¶2 as set forth at pp. 6-7 ¶21-25 in the previous Office Action (17 September 2003) is *moot* in view of Applicant's amendment of said claim (14 June 2004).
6. The Rejection under 35 U.S.C. §101 and §112 ¶2 as set forth in the previous Office Action (17 September 2003) is *withdrawn* in view of Gabellini *et al.* (18 September 2002) "The human SLC8A3 gene and the tissue-specific Na⁺/Ca²⁺ exchanger 3 isoforms." Gene 298(1):1-7,

Art Unit: 1647

Gabellini *et al.* (November 2002) "The gene promoter of human Na⁺/Ca²⁺ exchanger isoform 3 (SLC8A3) is controlled by cAMP and calcium." Ann N Y Acad Sci **976**: 282-4, and Gabellini *et al.* (January 2003) "Control of the Na⁺/Ca²⁺ exchanger 3 promoter by cyclic adenosine monophosphate and Ca²⁺ in differentiating neurons." J Neurochem **84**(2): 282-93. The Gabellini *et al.* references teaches nucleic acid and amino acid sequences which share more than 98% homology to the instantly claimed sequences thus confirming the predicted function and specificity of the nucleic acid sequence of SEQ ID NO: 1 and 3 which encode a human sodium/calcium exchanger of the amino acid sequences of SEQ ID NO: 2 and 4 [MPEP §2107].

New Objections And/Or Rejections

Oath/Declaration

7. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Inventor Erin Hilbun did not sign the Oath/Declaration.

Claim Rejections - 35 USC § 112

8. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. The term "hybridizes" in claim 2 is a relative term which renders the claim indefinite. The conditions under which the desired nucleic acids "hybridize" is not defined by the claim, the

Art Unit: 1647

specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

10. To satisfy the requirements of 35 U.S.C. §112 ¶2 Applicant must unambiguously define the limitations of the claims. Conditions for hybridization, while known the art, are not unambiguously defined. A great deal of latitude and a range of conditions may be construed as stringent. Also, stringency may be low, moderate, or high, none of which is specified by the claims as instantly neither presented nor supported by the Specification. For instance, the Roche website defines hybridization conditions under four parameters: temperature, pH, concentration of monovalent cations, and the presence of organic solvents, none of which are defined by the claims or the Specification ("Nucleic Acid Hybridization- General Aspects" pp. 33-37 Roche website retrieved on 12 May 2004). Also the NIH Division of Intramural Research teaches that "Nucleic Acid Hybridization" conditions vary. For temperature it teaches that it may be 25°C below duplex melting temperature, which varies due to the length of the polynucleotide and the GC content. Also, salt concentrations may vary between 5 to 6x SCC and denaturing agents such as formamide ranges from 1% to 50% (NIH Division of Intramural Research "Nucleic Acid Hybridization" retrieved from NIH website on 12 May 2004).

11. Furthermore Umansky *et al.* US 6,287,820 states:

Numerous equivalent conditions can be employed to comprise either low or high stringency conditions; factors such as the length and nature (DNA, RNA, base composition) of the probe and nature of the target (DNA, RNA, base composition, present in solution or immobilized, etc.) and the concentration of the salts and other components (e.g., the presence or absence of formamide, dextran sulfate, polyethylene glycol) are considered and the hybridization solution can be varied to generate conditions of either low or high stringency hybridization different from, but equivalent to, the above listed conditions. The term "hybridization" as used herein includes "any process by which a strand of nucleic acid joins with a complementary strand through base pairing"

Art Unit: 1647

(Coombs, Dictionary of Biotechnology, Stockton Press, New York N.Y. [1994].

"Stringency " typically occurs in a range from about $T_m - 5^\circ\text{C}$. (5. degree. C. below the T_m of the probe) to about 20. degree. C. to 25. degree. C. below T_m . As will be understood by those of skill in the art, a stringent hybridization can be used to identify or detect identical polynucleotide sequences or to identify or detect similar or related polynucleotide sequences.

12. Therefore, hybridization can be used to detect similar or related polynucleotide sequences, but there is no definite limit as to how similar or related the polynucleotide sequences have to be, and the claims are indefinite.

13. Therefore the skilled artisan is not apprised of the metes and bounds of what constitutes the conditions necessary for hybridization. Neither the specification nor the art defines the term unambiguously. Thus the metes and bounds of the claims cannot be determined. Incorporation of those conditions which Applicant feels defines the term hybridize into the claims would obviate the rejection (such as "0.5 M NaHPO_4 , 7% sodium dodecyl sulfate (SDS) 1 mM EDTA at 65°C ; washing in 0.1xSSC/0.1% SDS at 68°C " found at pp. pp. 5 lines 13-15 of the instant Specification).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 1647

14. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0119518

Stefan *et al.*

15. US 2002/0119518 teaches a sequence (SEQ ID NO: 1; 2782 bp; [0028]-[0035]) which has 99.8% sequence homology to the instantly claimed nucleic acid of SEQ ID NO: 1, a sequence (SEQ ID NO: 2; 921 aa) which has 100% sequence homology to the instantly claimed amino acid of SEQ ID NO: 2, a sequence (SEQ ID NO: 1; 2782 bp; [0028]-[0035]) which has 95.7% sequence homology to the instantly claimed nucleic acid of SEQ ID NO: 3, a sequence (SEQ ID NO: 2; 921 aa) which has 100% sequence homology to the instantly claimed amino acid of SEQ ID NO: 4.

16. US 2002/0119518 teaches nucleic acid sequences which are at least 90% or greater sequence homology to sequences therein thus meeting the limitations of claims 1 and 9 ([0088]-[0092]). US 2002/0119518 also teaches amino acid sequences which are at least 90% or greater sequence homology to sequences therein thus meeting the limitations of claims 3 and 4 ([0088]-[0092]).

17. US 2002/0119518 teaches nucleic acids which hybridize to the above sequences meeting the limitations of claim 2 ([0167]).

18. US 2002/0119518 teaches vectors and host cells transformed for the above sequences meeting the limitations of claims 5-8 ([0217]-[0249]).

19. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 02/46415

Lee *et al.*

Art Unit: 1647

20. WO 02/46415 teaches a sequence (claim 96; SEQ ID NO: 41; 2966 bp) which has 99.9% sequence homology (a single bp change of T to C at position 1053) to the instantly claimed nucleic acid of SEQ ID NO: 1, a sequence (claim 64; SEQ ID NO: 9; 921 aa) which has 100% sequence homology to the instantly claimed amino acid of SEQ ID NO: 2, a sequence (claim 96; SEQ ID NO: 41; 2966 bp) which has 95.7% sequence homology to the instantly claimed nucleic acid of SEQ ID NO: 3, and a sequence (claim 64; SEQ ID NO: 9; 921 aa) which has 100% sequence homology to the instantly claimed amino acid of SEQ ID NO: 4.

21. WO 02/46415 teaches nucleic acid sequences which are at least 90% or greater sequence homology to sequences therein thus meeting the limitations of claims 1 and 9 (pp. 14-17; 34). WO 02/46415 also teaches amino acid sequences which are at least 90% or greater sequence homology to sequences therein thus meeting the limitations of claims 3 and 4 (pp. 14-17; 34).

22. WO 02/46415 teaches nucleic acids which hybridize to the above sequences meeting the limitations of claim 2 (pp. 29).

23. WO 02/46415 teaches vectors and host cells transformed for the above sequences meeting the limitations of claims 5-8 (pp. 32; 43-48; 57; 85-87).

24. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 02/33086 Merkulov *et al.*

25. WO 02/33086 teaches a sequence (claim 4; Figure 1; 2782 bp; pp. 5) which has 99.9% sequence homology (a single bp change of T to C at position 956) to the instantly claimed nucleic acid of SEQ ID NO: 1, a sequence (claim 4; Figure 2; 921 aa; pp. 5) which has 100% sequence homology to the instantly claimed amino acid of SEQ ID NO: 2, a sequence (claim 4;

Art Unit: 1647

Figure 1; 2782 bp; pp. 5) which has 98.4% sequence homology to the instantly claimed nucleic acid of SEQ ID NO: 3, and a sequence (claim 4; Figure 2; 921 aa; pp. 5) which has 100% sequence homology to the instantly claimed amino acid of SEQ ID NO: 4.

26. WO 02/33086 teaches nucleic acid sequences which are at least 90% or greater sequence homology to sequences therein thus meeting the limitations of claims 1 and 9 (pp. 17-18). WO 02/33086 also teaches amino acid sequences which are at least 90% or greater sequence homology to sequences therein thus meeting the limitations of claims 3 and 4 (pp. 17-18).

27. WO 02/33086 teaches nucleic acids which hybridize to the above sequences meeting the limitations of claim 2 (pp. 37).

28. WO 02/33086 teaches vectors and host cells transformed for the above sequences meeting the limitations of claims 5-8 (pp. 47-52).

Summary

29. No claims are allowed.

Art Unit: 1647


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
July 13, 2004


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SUPERVISORY PATENT EXAMINER
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